UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 22-10697-RGS

TRACY HUNT

v.

COVIDIEN LP, COVIDIEN SALES LLC,
COVIDIEN HOLDING INC., and MEDTRONIC, INC.

MEMORANDUM AND ORDER ON DEFENDANTS'
MOTION FOR SUMMARY JUDGMENT and
MOTIONS TO EXCLUDE PROPOSED EXPERT TESTIMONY OF
STEPHEN V. HAMN, JASON Z. MOORE, AND LAURA PLUNKETT

May 28, 2024

STEARNS, D.J.

On May 9, 2019, Dr. Juozas Zavadzkas performed a laparoscopic hiatal hernia repair and a laparoscopic sleeve gastrectomy on plaintiff Tracy Hunt. Dr. Zavadzkas used three surgical stapler devices during the gastrectomy: (1) a EGIAUXL stapler handle (the Handle), (2) the purple Tri-Staple SIGTRSB60AMT stapler cartridge, and (3) the black Tri-Staple SIGTRSB60AXT stapler cartridge (together, the Cartridges; and together with the Handle, the Products). The Products were designed, manufactured, and marketed by defendants Covidien LP, Covidien Sales LLC, Covidien Holding Inc., and Medtronic, Inc. (together, Covidien).

Immediately following the surgery, Hunt was beset with extreme abdominal pain. Less than two weeks later, she presented at a local emergency room with her abdominal pain compounded by a high fever. Believing that a staple line leak had caused her injuries, she sued Covidien. She alleges that Covidien defectively designed and manufactured the Products (Count I); failed to warn of the Products' non-obvious dangers (Count II); negligently designed, manufactured, marketed, labeled, packaged, and sold the Products (Count III); and engaged in deceptive trade practices in violation of Mass. Gen. Laws ch. 93A (Count IV).

At the close of fact discovery, Covidien moved to exclude the testimony of three of Hunt's expert witnesses – Drs. Stephen Hamn, Jason Moore, and Laura Plunkett – and for summary judgment on all claims. The court will deny the motion to exclude the testimony of Dr. Hamn, allow the motion to exclude the testimony of Dr. Moore in part and deny it in part, allow the motion to exclude the testimony of Dr. Plunkett, and allow the motion for summary judgment in part.

BACKGROUND

Regulatory Background

During the relevant period, the U.S. Food and Drug Administration (FDA) classified the Handle as a Class I medical device and the Cartridges as

Class II medical devices.[1] The FDA cleared the Products for marketing through the 510(k) process.[2] *See* Mem. in Support of Covidien's Mot. for Summ. J. (Summ. J. Mot.) (Dkt. # 107) at 4.

The FDA requires medical device manufacturers to report adverse outcomes that may be attributable to their devices. *See* 21 C.F.R. pt. 803.10, 803.50. Until 2019, the FDA permitted approved manufacturers to report certain types of adverse results through its Alternative Summary Reporting (ASR) Program. All reports submitted through the ASR Program were not publicly available until 2019.

In March of 2001, the FDA invited Covidien to report any adverse events involving the Products through the ASR Program. Hunt alleges that each year from 2013 through 2017, Covidien reported thousands of Products-related adverse events through the ASR Program. *See* Pl.'s Mem. in Support

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[1] A Class I device is the least dangerous type of medical device and is subject only to the FDA's "general controls." 21 U.S.C. § 360c(a)(1)(A). A Class II device is potentially more dangerous and must comply with heightened "special controls." *Id.* § 360c(a)(1)(B).

[2] The 510(k) process subjects a medical device that is "substantially equivalent" to a pre-existing device to a "limited form of [FDA] review." *Medtronic v. Lohr*, 518 U.S. 470, 478 (1996). The parties differ over whether the FDA "cleared" the products through this process. As the FDA refers to the 510(k) process as a "clearance," the court will as well. *See, e.g.*, FDA, The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications: Guidance for Industry and Food and Drug Administration Staff 4 (2014).

of her Resp. to Defs.' Mot. for Summ. J. (Summ. J. Opp'n) (Dkt. # 124) at 4. During the same period, according to Hunt, Covidien reported less than 200 adverse events annually on the FDA's public Manufacturer and User Facility Device Experience (MAUDE) database.

The Products

The Products came with Instructions for Use (IFUs), which warned surgeons of the risk of staple line leaks. *E.g.*, Summ. J. Mot., Ex. D (Dkt. # 107-3). Dr. Zavadzkas read the IFUs, but he did not rely on them while performing Hunt's gastrectomy, *see* Summ. J. Mot., Ex. K (Zavadzkas Dep.) (Dkt. # 107-10) at 68:2-68:11, nor did he rely on any of Covidien's marketing materials or review any of the reported adverse events implicating the Products, *see id.* at 68:12-15, 69:23-70:8. Dr. Zavadzkas, however, was aware – and informed Hunt – of the risk of a staple line leak. *Id.* at 36:12-15.[3]

Covidien defines a properly formed staple as one that is "wholly and symmetrically formed in one plane whose tips terminate at the backspan in the form of a capital 'B.'" Summ. J. Opp'n, Ex. 19 (Dkt. # 124-19) at 20. A

[3] Hunt also claims that Covidien failed to warn Dr. Zavadzkas that "the stapler handle used in Ms. Hunt's 2019 surgery" had been recalled at the time. Summ. J. Opp'n at 5-6. The FDA had recalled certain lots of the Handle, but Hunt presents no evidence that the Handle used by Dr. Zavadzkas to perform her surgery was among the recalled lots.

partially formed staple is one "which has one leg properly formed with the tip touching the backspan and one leg undercrimped with the tip less than parallel to the backspan." *Id.* Covidien considers both properly and partially formed staples "acceptable." *Id.* Several factors can influence whether a staple will properly form: the integrity of the staple, the thickness of the tissue being fastened, and the pressure applied by the surgeon while inserting the staple. *See* Summ. J. Opp'n at 24-28. If the staple is malformed, it may tear or fail to fully seal the tissue, which can result in leaks. *See id.* at 6.

Covidien tests its Products during a quality control process. The testing involves the propulsive firing of the Products into red foam;[4] counting the number of staples that are over- or undercrimped, twisted, or "off 'B'"; measuring the distance of the malformation; and calculating the overall percentage of malformed staples. *See* Summ. J. Opp'n, Ex. 19 at 1, 20. Covidien does not include partially formed staples in calculating the percentage of malformed staples. *See id.*

[4] Red foam is "the leading testing medium used to evaluate [the Products] by Medtronic." Pl.'s Resp. to Defs.' Mot. to Exclude Jason Z. Moore, Ph.D. (Moore Opp'n), Ex. 5 (Moore Report) (Dkt. # 122-5) at 12.

Hunt's Surgeries

To perform the laparoscopic sleeve gastrectomy, Dr. Zavadzkas used the Products to dissect and remove sections of Hunt's stomach and then stitch the cuts with staples. According to Dr. Zavadzkas, the Products worked "exactly as [he] expected [them] to work." Zavadzkas Dep. at 60:10-18. Dr. Zavadzkas does not recall whether he inspected the Cartridges, but he testified that had he noticed any abnormality, he would have dictated his observations into the medical record. *Id.* at 60:22-61:2. He did note that when he completed the staple line, he visually inspected and tested it and did not detect a leak. After the surgery, when Hunt reported experiencing severe pain, his colleagues again tested for a staple line leak and found none. *See* Summ. J. Mot., Ex. Q (Dkt. # 107-16).

Thirteen days after the surgery, Hunt presented at the emergency room complaining of severe abdominal pain and a high fever. The parties dispute whether at the time Hunt was suffering an esophageal leak or a staple line leak. Some portions of Hunt's medical records refer to a leak near both the esophagus and stomach. *See* Summ. J. Mot., Ex. S (Dkt. # 107-18). Others refer to a leak on her esophagus. *See* Summ. J. Mot., Ex. T (Dkt. # 107-19). The bulk of the records, however, refer to "staple line failure" or "leak," an "abscess at the anastomotic site," or an "anastomotic leak." *See, e.g.*, Pl.'s

Mem. in Supp. of her Response to Defs.' Mot. to Exclude Dr. Stephen Hamn (Hamn Opp'n), Ex. 6 (Dkt. # 120-6) at 7, 11, 14, 17, 21, 27. Over time, Hunt's leak resolved itself without any further surgical intervention. Summ. J. Mot. at 10.

DISCUSSION

Motions to Exclude Expert Testimony

Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), imposes a duty on federal trial judges to play the role of "gatekeeper," insuring that the fact-finding process does not become distorted by "expertise that is *fausse* and science that is junky." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 159 (1999) (Scalia, J., concurring). Two gateposts frame the exercise of a judge's discretion to admit or exclude expert testimony. First, the witness must be shown to be sufficiently qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. Second, the Federal Rules of Evidence require that the judge "ensure that any and all scientific testimony or evidence admitted is not only relevant, but [also] reliable." *Daubert*, 509 U.S. at 589.

> [T]he trial judge must determine at the outset, pursuant to Rule 104(a), whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and

> of whether that reasoning or methodology properly can be applied to the facts in issue.

Id. at 592-593 (footnotes omitted). "Reliability is as much a part of the broader determination of admissibility of the expert's opinion as it is of the determination as to the reliability of the methodology employed, and trial judges 'have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.'" *LightLab Imaging, Inc. v. Axsun Techs., Inc.*, 469 Mass. 181, 190 (2014), quoting *Kumho Tire*, 526 U.S. at 152.[5]

An expert need not be a "'blue-ribbon practitioner[]' with optimal qualifications" or be hyper-specialized in the field to satisfy Rule 702(a). *United States v. Vargas*, 471 F.3d 255, 262 (1st Cir. 2006), quoting *United States v. Mahone*, 453 F.3d 68, 71 (1st Cir. 2006); *see also Gaydar v. Sociedad Instituto Gineco-Quirurgico y Planificacion Familiar*, 345 F.3d 15, 24 (1st Cir. 2003) (qualifying a doctor as an expert on ectopic pregnancies

[5] Rule 702 was amended in 2023 to clarify that Rule 104(a)'s preponderance standard applies to all prongs of Rule 702's requirements. But the amendment does not foreclose, as Covidien claims, "*any* contention that arguments based on Rule 702 go 'to weight, not admissibility.'" *E.g.*, Defs.' Rule 702 Mem. in Supp. of Their Mot. to Exclude Proposed Expert Testimony of Stephen V. Hamn, M.D. (Hamn Mot.) (Dkt. # 104) at 1 n.1 (emphasis added); *see* Fed. R. Evid. 702 notes on 2023 amendment ("Some challenges to expert testimony will raise matters of weight rather than admissibility even under the Rule 104(a) standard.").

although he did not specialize in gynecology). All that is required is that the expert has "achieved a meaningful threshold of expertise" in the field. *Alvarez v. R.J. Reynolds Tobacco Co.*, 405 F.3d 36, 40 (1st Cir. 2005).

In assessing methodological reliability, the court may consider whether the method (1) "can be (and has been) tested," (2) is subject to peer review and publication, (3) has a "known or potential rate of error," and (4) is generally accepted in the field. *Daubert*, 509 U.S. at 593-594. None of these factors is dispositive. *See Cipollone v. Yale Indus. Prods., Inc.*, 202 F.3d 376, 380 (1st Cir. 2000). The court's "focus, of course, must be solely on principles and methodology, not on the conclusions that they generate," *Daubert*, 509 U.S. at 595.

(1) Dr. Hamn

Hunt retained Dr. Stephen Hamn, a board-certified general surgeon who has practiced for 40 years, to give expert testimony on the issue of causation. Dr. Hamn conducted a differential diagnosis[6] to come to an opinion as to the most likely cause of Hunt's injuries. Hamn Mot., Ex. L (Hamn Dep.) at 136:8-11. He concluded that Hunt "suffered a staple line leak

[6] A differential diagnosis is "essentially a process of elimination" whereby an expert "rules in" and "rules out" potential causes of a medical condition and then determines the most likely cause. *See Milward v. Rust-Oleum Corp.*, 820 F.3d 469, 472 (1st Cir. 2016).

in a critical area from the stapler" and that it was more likely than not that the leak "was due to staple malformation during the firing of the [Handle] in combination with the reinforced Tri-Staple Reloads." Hamn Opp'n, Ex. 4 (Hamn Report) (Dkt. # 120-4) at 4.

Covidien's main objection[7] to Dr. Hamn's testimony focuses on the reliability of Dr. Hamm's application of a differential diagnosis.[8] Relying on *Milward v. Rust-Oleum Corp.*, 820 F.3d 469 (1st Cir. 2016), Covidien argues that Dr. Hamn should have independently determined that staple malformation was a likely cause of Hunt's injuries before ruling it into his formula. *See* Hamn Mot. at 12. In *Milward*, the proffered expert selectively relied on scientific literature to rule in benzene exposure as the likely cause of plaintiff's leukemia. *Milward*, 820 F.3d at 473-474, 476. She ruled out

[7] Covidien also contends that Dr. Hamn speculated that Hunt's post-surgical leak was located on the staple line. Dr. Hamn's report states that he relied on the many medical records that diagnosed Hunt with a staple line leak. *See, e.g.*, Hamn Opp'n, Ex. 13 (Dkt. # 120-13). Medical records are a "reliable basis" on which a medical expert may base his opinions. *See Kumho Tire*, 526 U.S. at 148; *see also Rodriguez v. Hosp. San Crisobal, Inc.*, 91 F.4th 59, 71-72 (1st Cir. 2024) ("Questions about the strength of the factual underpinning of an expert's opinion are matters affecting the weight and credibility of the testimony and therefore are questions to be resolved by the jury.") (cleaned up).

[8] Covidien appears to also suggest that a differential diagnosis is an inherently unreliable methodology. The First Circuit has rejected this argument. *See, e.g.*, *Granfield v. CSX Transp., Inc.*, 597 F.3d 474, 486 (1st Cir. 2010).

the possibility of idiopathic leukemia based solely on ruling in benzene as the foundation of her diagnosis. The exclusion of idiopathic leukemia was problematic because 70-80% of leukemia cases are idiopathic. *Id.* at 475. Since she "was only able to 'rule out' an idiopathic [leukemia] because she had 'ruled in' benzene as a cause, the validity of her differential diagnosis turn[ed] on the [dubious] reliability of that latter conclusion." *Id.*

That, however, is not an accurate description of how Dr. Hamn proceeded in coming to his diagnosis. He first "list[ed] and consider[ed] all the possible causes of [Hunt's] symptoms" and then "set about ruling out the least likely using history, physical exam, testing, and experience." Hamn Opp'n, Ex. 11 (Hamn Aff.) (Dkt. # 120-11) ¶ 3. Relying on his experience and the relevant medical literature, Dr. Hamn ruled in patient non-compliance, "the performance of the doctor, the biology of the patient, [and] the [failure of the] medical device used to create the seal." *Id.* ¶ 5; Hamn Dep. at 100:6-23. The court is satisfied that Dr. Hamn's differential diagnosis methodology was reliably applied.

Covidien persists, objecting to Dr. Hamn's decision to rule out patient noncompliance. Hamn Mot. at 15. Covidien, however, concedes that Dr. Hamn searched for evidence of noncompliance and found none, and it does not point to evidence of noncompliance that Dr. Hamn failed to identify

and consider. *See id.* at 15-16. Covidien also contends that Dr. Hamn failed to rule out an idiopathic leak. *See id.* at 15. This appears to be true, but Dr. Hamn "was not required to eliminate every other possible cause." *Packgen v. Berry Plastics Corp.*, 847 F.3d 80, 87 (1st Cir. 2017). This is not a case like *Milward*, in which it was undisputed that most staple line leaks are idiopathic. Covidien is free to probe whether Hunt's leak may have been idiopathic on cross-examination. But this "only goes to the accuracy of [Dr. Hamn's] conclusion, not the soundness of [his] methodology." *Id.*, quoting *Ambrosini v. Labarraque*, 101 F.3d 129, 140 (D.C. Cir. 1996). Covidien's motion to exclude Dr. Hamn will thus be denied.

(2) Dr. Moore

Hunt's next proffered expert is Dr. Jason Moore, a professor of mechanical engineering at Penn State University. Dr. Moore researches medical device designs and specializes in the interactions between medical devices and soft tissue. He has developed, patented, and manufactured medical devices, and he co-owns a business that develops products to simulate medical procedures. He has provided expert opinions in prior cases on general and specific causation, design and manufacturing defects, alternative designs, and quality assurance.

Covidien first challenges Dr. Moore's qualifications under Rule 702(a). The court readily concludes that Dr. Moore's academic specialization and depth of practical experience provide the requisite foundation for his opinions regarding general causation and possible design defects.[9] He also has sufficient expertise regarding mechanical device interactions with soft tissue to testify about feasible alternative designs.

Dr. Moore also proposes to offer three quality assurance opinions, namely that Medtronic's testing procedure is defective because (1) in calculating a passing testing grade "[a]n unlimited number of staples can be Partially Formed," (2) the medium used to test staple formation (red foam) "does not adequately replicate staple malformations seen in real tissue," and (3) it lacks repeatability, includes limited testing, and allows for operator bias. Moore Report at 10, 14. The first two opinions fall squarely within his expertise. However, he lacks the expertise to support his third opinion. He has never designed a quality assurance program, has not published in the field, and has never inspected (or even visited) a stapler manufacturing facility.

[9] To the extent Moore intends to opine that a "recall" shows the Products were defectively designed, he is not permitted to do so. *See supra* n. 3.

The court also agrees with Covidien that Dr. Moore is not qualified to render opinions on specific causation, the existence of a manufacturing defect, or the adequacy of the IFUs. Dr. Moore is not a medical doctor and cannot credibly testify as to any specific cause of Hunt's injuries. *See Levin v. Dalva Bros., Inc.*, 459 F.3d 68, 78 (1st Cir. 2006). Dr. Moore conceded at his deposition that he was not aware of any manufacturing defect in the Products. *See* Moore Opp'n, Ex. 7 (Moore Dep.) at 296:2-4 ("I'm not able to discern the specific parts that might have led to the leak that was factually seen in Ms. Hunt's case."). He only speculates that Medtronic's quality assurance procedures might have failed to identify such a defect. *See id.* at 297:1-9. Manufacturing defect claims are inherently product-specific: Hunt must show that the one or more of the Products used to operate on Hunt "deviat[ed] from [its] design" in a way that was "unreasonably dangerous." *See Back v. Wickes Corp.*, 375 Mass. 633, 641 (1978). General testimony that a manufacturing defect could have occurred is not of any help to the finder of fact. Finally, as to the IFUs, Dr. Moore has no experience drafting or designing IFUs, and he has never reviewed IFUs for any surgical stapler other than in preparing an opinion in Hunt's case.

The court will now turn from the issue of Dr. Moore's expert qualifications to the reliability of his application of his chosen methodology

under Rule 702(c) and (d). Dr. Moore employed a six-step "failure analysis" that is referenced in standard material science textbooks, was taught to him, and is now taught by him. *See* Moore Dep. at 206:4-16; Aff. of Jason Z. Moore Ph.D. (Moore Aff.) (Dkt. # 122-6) ¶ 6. In doing so, Dr. Moore "focused on understanding the behavior, quality and essence of the device and its interactions with the user and tissue rather than performing a statistical or metric based analysis." Moore Aff. ¶ 7. Because Hunt has proffered evidence that the method is "generally accepted in the relevant engineering community," and that Dr. Moore's preparation is "of a kind that others in the field would recognize as acceptable," the court finds the methodology reliable. *See Kumho Tire Co.*, 526 U.S. at 151.

In performing the failure analysis, Dr. Moore relied on his knowledge and experience to reach conclusions based on internal Covidien documents and medical device literature. *See* Moore Report App'x B; Moore Aff. ¶ 7. An opinion "grounded exclusively on scientific literature" may be admissible unless the expert improperly disregarded "incompatible research." *Milward*, 820 F.3d at 474. Covidien does not contend that Dr. Moore ignored literature that conflicted with his conclusions. The court is satisfied that Dr. Moore reliably applied a failure analysis methodology.

(3) Dr. Plunkett

Dr. Laura Plunkett is an FDA regulatory specialist and co-founder of the consulting firm BioPolicy Solutions LLC. In her consulting practice, she has undertaken projects for clients advising on the regulation of medical devices, the design of preclinical and clinical studies, and the efficacy of product warnings. Hunt retained Dr. Plunkett to opine on "the regulation of medical devices by the FDA." Defs.' Rule 702 Mem. in Supp. of Their Mot. to Exclude the Proposed Expert Test. of Dr. Laura Plunkett (Plunkett Mot.), Ex. A (Plunkett Report) (Dkt. # 105-1) ¶ 10. Dr. Plunkett performed a human health risk assessment and a weight-of-the-evidence assessment. In performing these analyses, she reviewed scientific literature, FDA regulations and guidance, the Products' labeling, and "information on surgical stapler devices." *Id.* ¶ 11.

Dr. Plunkett's lengthy report provides extensive background on the FDA's regulation of medical devices, including the MAUDE database, the ASR Program, and the 510(k) process. She is critical of both the 510(k) process and the ASR Program,[10] contending that, because of systemic

[10] Regarding the 510(k) process, she notes that because surgical staplers are Class I products, manufacturers like Covidien are not required to notify the FDA about Product modifications. Plunkett Report ¶ 24. As for the ASR Program, Dr. Plunkett notes that while over one million nonpublic

underreporting by medical device manufacturers, only "1 in 100 medical device adverse events [are] reported." *Id.* ¶ 36. While Dr. Plunkett does not conceal her contempt for the FDA, her critiques for the most part are framed in the polemical abstract untethered to the Products. Indeed, she makes no substantive mention of the Products until page 36 of her report.

Dr. Plunkett next provides "specific concerns" about Covidien's testing and complaint-handling processes. These are: (1) Covidien generally did not test the Cartridges; (2) Covidien inadequately tested the Purple Cartridge because a failure to mimic "real-world" conditions and it "may have" tested too small a number of staplers[11] that were not randomly selected in the first place; (3) Covidien handled "legal" adverse events complaints (*i.e.*, those that it learned of when it was sued) differently than those that were reported directly; and (4) Covidien outsourced complaint handling to a company in the Philippines. *See id.* ¶¶ 63-82. She further opines that Covidien failed to adequately warn physicians of patient risks because: (1) the IFUs did not warn about the dangers of tissue thickness; (2) the IFUs did not inform

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adverse event reports were made to the FDA from 2016-2019, the FDA had only 15 staff members assigned to review these reports. *Id.* ¶ 34.

[11] Dr. Plunkett uses the undefined term "staplers" in this portion of her report. It is not clear whether she means the Handle, the Cartridges, or the Products as a collective whole.

physicians of the shortcomings of Covidien's quality control testing; and (3) despite being aware that physicians were not reading the IFUs, Covidien made no effort to "provide updates to physicians." *See id.* ¶¶ 95, 98-99.

The difficulty with Dr. Plunkett's report is its lack of any mooring in the facts of this case. Dr. Plunkett's critiques of the 510(k) process, the ASR Program, and alleged underreporting of adverse events by medical device manufacturers in general are personal opinions that, unconnected to the Products at issue, may be of interest but not of any help to the jury.[12] As to her testing opinions, Dr. Plunkett opines that red foam "does not mimic human tissue," and that Covidien did not test enough staplers or randomly select the staplers it tested. *Id.* ¶¶ 67, 70. But she does not identify any FDA regulation prohibiting (or even advising against) the use of red foam as a testing medium, explain how red foam testing may have had any connection

[12] For example, Dr. Plunkett never states how many adverse events related to staple malformation Covidien reported through the ASR Program, nor does she offer any evidence that Covidien misreported events to the ASR Program. Without a single example, her vague conclusion that Covidien's use of the ASR Program "compounded the problem of a lack of physician awareness of accurate [Stapler] system performance and safety" is too attenuated from this case to be useful. *See id.* ¶ 78. The same is true for her opinion that Covidien's complaint handling process was deficient. Dr. Plunkett seems to imply that Covidien did not have a person "qualified to make a medical judgment" involved in the complaint-handling process, but she never definitively opines as much. *See id.* ¶ 75.

to Hunt's injuries, or explain how the issues with the tests' design caused Covidien to fail to warn physicians of the potential risks of the Products.

What remains is Dr. Plunkett's opinions as to Covidien's failure to adequately warn physicians of Product risks. As Covidien points out, "indisputable record facts contradict" Dr. Plunkett's opinion that the IFU fails to warn about the effect that tissue consistency could have on proper staple formation. *See Brooke Grp. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209, 242 (1993); Pl.'s Mem. in Supp. of her Resp. to Defs.' Mot. to Exclude Expert Testimony of Dr. Laura Plunkett, Ex. 2 (Dkt. # 121-2) (IFU states clearly that "overly thick or thin tissue may result in unacceptable staple formation"). She also does not identify any adverse events of which she claims the IFUs needed warn.[13] The court will exclude the expert testimony of Dr. Plunkett as unhelpful.

[13] Dr. Plunkett cites one 2016 study which found that, from 2006-2016, Covidien reported to the MAUDE database more deaths and injuries caused by the Endo GIA staplers than three other surgical staple manufacturers. *See* Plunkett Report ¶ 66. This study is unhelpful on a number of levels. First, Covidien markets multiple Endo GIA staplers, and there is no evidence that the type of Endo GIA stapler used on Hunt caused any of these injuries. Second, these reports were public and available to physicians. Third, the study's dataset ends one year before Covidien updated its reinforcement material for the Purple Cartridge and three years before Hunt's surgery.

Motion for Summary Judgment

Summary judgment is warranted where the movant demonstrates that the record, "construed in the light most flattering to the nonmovant, 'presents no genuine issue as to any material fact and reflects the movant's entitlement to judgment as a matter of law.'" *Lawless v. Steward Health Care Sys.*, 894 F.3d 9, 20-21 (1st Cir. 2018), quoting *McKenney v. Mangino*, 873 F.3d 75, 80 (1st Cir. 2017). A factual dispute is "genuine" if there is "sufficient evidence supporting the claimed factual dispute . . . to require a jury or judge to resolve the parties' differing versions of truth at trial." *First Nat'l Bank of Arizona v. Cities Serv. Co.*, 391 U.S. 253, 289 (1968).

Covidien bears the burden of showing that there are no genuine disputes of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). It discharges this burden if it shows that Hunt has failed "to make a showing sufficient to establish the existence of an element essential to [her] case, and on which [she] will bear the burden of proof at trial." *Id.* at 322. The burden then shifts to Hunt to adduce facts that "find adequate support in the record . . . showing that a trier of fact reasonably could find in [her] favor." *Murray v. Warren Pumps, LLC*, 821 F.3d 77, 83 (1st Cir. 2016).

The parties first dispute whether Massachusetts or North Carolina law governs the dispute. The parties appear to agree that a choice of law would

not impact the outcome of the case, so a "[c]hoice of law analysis is unnecessary." *Kaufman v. Richmond*, 442 Mass. 1010, 1011 (2004). As Hunt plead her claims under Massachusetts law, the court will follow suit.

(1) Counts I and II: Breach of Implied Warranty

In a contract for the sale of goods, Massachusetts law implies a warranty that the goods are fit for the ordinary purposes for which such goods are used. *Haglund v. Philip Morris, Inc.*, 446 Mass. 741, 746 (2006). The seller breaches the implied warranty if the goods are "'defective and unreasonably dangerous' . . . for the '[o]rdinary purposes' for which [they are] 'fit.'" *Evans v. Lorillard Tobacco Co.*, 465 Mass. 411, 422 (2013), quoting *Haglund*, 446 Mass. at 746 (first and second alterations in original). Where the "nature of the defect or breach of warranty and its causal relation to the [injury is] complex," as the parties seem to agree is the case here, "failure to adduce expert testimony . . . [is] fatal to [plaintiff's] case." *Hochen v. Bobst Grp.*, 290 F.3d 446, 451 (1st Cir. 2002); *Wiska v. St. Stanislaus Soc. Club, Inc.*, 7 Mass. App. Ct. 813, 821 (1979). A product may be defective and unreasonably dangerous because of a manufacturing defect, design defect, or "failure reasonably to warn of the product's foreseeable risks of harm." *Evans*, 465 Mass. at 422. Hunt pursues all three theories.

Design Defect

A manufacturer is liable for defectively designing a product if its "'conscious design choices' fail to anticipate the reasonably foreseeable risks of 'ordinary' use" and the plaintiff is injured as a result. *Haglund*, 446 Mass. at 747-748, quoting *Back*, 375 Mass. at 640, 642. Hunt identifies two design defects: (1) the Products fail to ensure the staple line will properly seal and (2) Covidien's quality controls fail to ensure that the staples form properly.

"The 'fitness' of the product 'is a question of degree, depending largely, although not exclusively, on reasonable consumer expectations.'" *Marchant v. Dayton Tire & Rubber Co.*, 836 F.2d 695, 698 (1st Cir. 1988), quoting *Back*, 371 Mass. at 642. To assess the Products' design, the court considers

> the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design.

Back, 375 Mass. at 642, quoting *Barker v. Lull Eng'r Co.*, 20 Cal. 3d 413, 431 (1978). Hunt must show that a reasonable alternative design "'was, or reasonably could have been, available at time of sale or distribution,' that would have reduced the foreseeable risks of harm posed by the product at a reasonable cost," but she need not show that any manufacturer "employed it

or even considered it." *Evans*, 465 Mass. at 424, quoting Restatement (Third) of Products Liability § 2(b); *see also Haglund*, 446 Mass. at 748.

The Cartridges each have three staples of varied heights. The Purple Cartridge can be used on tissue 1.5-2.3mm thick, and the Black Cartridge can be used on tissue 2.3-3mm thick. *See* Moore Report at 8. Because the smallest staple is placed closest to where the cut is made, Dr. Moore explains, it is the "most critical to ensuring a successful seal." *Id.* But, according to a Medtronic design engineer, the smallest of the three staples may be fired into tissue thicker than it can effectively seal. *See id.*

The Products provide no feedback about tissue thickness to the physician, so the physician must, while operating laparoscopically, "utilize[e] only visual inspection and indirect tactile feedback." *Id.* at 4. And as there is no overlap in the acceptable thickness between the Purple and Black Cartridges, if the physician misjudges the tissue thickness and uses the incorrect Cartridge, the staple line will not seal.[14] *See id.* at 9.

Dr. Moore proposes two safer alternative designs: a "low technology" system to limit the amount of force a physician can apply to tissue and

[14] This is not to suggest that Dr. Zavadzkas erred in judging which Cartridge to use (and the parties do not argue as much). Hunt's argument is that the Products were defectively designed because they do not give physicians adequate tools to determine tissue thickness.

automating firing to slow the firing rate. *See id.* at 17-18. In other staplers it manufactures, Medtronic already implements the automated firing technology. Based on Dr. Moore's testimony, a reasonable jury could conclude that the Products were unreasonably dangerous because Covidien failed to design them to fire only into appropriately thick tissue, knew of the risks of the design, and failed to adopt a safer alternative design.

This leaves causation. As to "but-for" causation, Dr. Moore's and Dr. Hamn's opinions, taken together, are that the design defect could cause staple malformation and that a staple malformation was the cause of Hunt's leak. If a jury credits their testimony, this is enough to show by a preponderance of the evidence that but for the defect, Hunt would not have been injured. As to proximate causation, Medtronic design documents and testimony from Medtronic engineers show that it was aware that one of the effects of a stapler firing over tissue that is too thick or thin is "[n]on-functional staple line closure." Moore Report at 5. Thus, a reasonable jury could find that Hunt's injury was foreseeable.

Regarding the second defect, Hunt faults Covidien's quality controls, but she does not explain how this impacts the design of the Products. Indeed, she argues that Covidien "design[s] the staplers to fire symmetrical staples

in a 'B' configuration." Summ. J. Opp'n at 24. No reasonable jury could conclude that this amounts to a design defect.

Manufacturing Defect and Failure to Warn

As noted, Hunt is required to present expert testimony to succeed on her manufacturing defect and failure to warn claims. *See Hochen*, 290 F.3d at 451. Hunt retained Dr. Moore to testify that the Products were defectively manufactured and Dr. Plunkett to testify that the Products' warnings were deficient. The court has found both opinions inadmissible, and Hunt offers no other expert testimony for the claims, so they are dismissed.

(2) Count III: Negligence

Because Hunt's negligence claim is based on her defective design, manufacture, and warning claims, the standard of proof for the negligence claim follows that of her breach of warranty claims. *See Evans*, 465 Mass. at 443-444; *Bavuso v. Caterpillar Indus., Inc.*, 408 Mass. 694, 699 n.8 (1990). Thus, to the extent that Hunt has a viable design defect claim, she has a viable negligence claim.

(3) Count IV: Chapter 93A

Count IV alleges that Covidien "improperly marketed and sold" the Products and that its conduct was unfair and deceptive because it "impliedly or expressly misrepresented [the Products] as being safe and effective for use

by patients." Third Am. Compl. (Dkt. # 29) ¶¶ 94-95. Hunt's argument appears to be that Covidien impliedly misrepresented the safety of the Products by using the ASR Program, and that Covidien's failure to warn of the Products' risks in the IFUs were express misrepresentations.

A successful Chapter 93A claim requires proof that Covidien invaded Hunt's "legally protected interests" and that invasion "caused [her] a loss—whether that loss be economic or noneconomic." *Hershenow v. Enter. Rent-a-Car Co. of Bos.*, 445 Mass. 790, 802 (2006). Causation is established where the act or practice "could reasonably be found to have caused a person to act differently from the way he [or she] otherwise would have acted." *Id.* at 801, quoting *Aspinall v. Philip Morris Cos.*, 442 Mass. 381, 394 (2004) (alteration in original).

Hunt stumbles on causation for both theories. Dr. Zavadzkas testified that he read the IFUs at some point but not before Hunt's surgery; that he has never looked up adverse event reports in the MAUDE database; that in the five years since the ASR Program reports have become public, he has never looked at any of the reports; and that he still uses the products today. *See* Zavadzkas Dep. at 68:2-6, 69:13-70:8. And Hunt does not contend that she ever saw the IFUs or tried to find any adverse event reports. There is

thus no evidence that Dr. Zavadzkas or Hunt would have acted differently had Covidien publicly reported all adverse events caused by the Products.

ORDER

For the foregoing reasons, Covidien's motion to exclude the testimony of Dr. Hamn is DENIED. Covidien's motion to exclude the testimony of Dr. Moore is ALLOWED IN PART and DENIED IN PART. Dr. Moore may opine on general causation, design defect, alternative designs, and that Covidien's quality assurance process was deficient because it permitted the Products to fire partially formed staples and used red foam testing. Covidien's motion to exclude the testimony of Dr. Plunkett is ALLOWED. Covidien's motion for summary judgment is ALLOWED IN PART and DENIED IN PART. Count I of the Complaint is hereby dismissed to the extent it alleges a manufacturing defect, and Counts II and IV of the Complaint are hereby dismissed in full.

SO ORDERED.

/s/ Richard G. Stearns
UNITED STATES DISTRICT JUDGE